DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

m5205

February 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 35

Sister Jean Juenemann
Chief Executive Officer
Queen of Peace Hospital
301 Second Street NE
New Prague, Minnesota 56071

Dear Sister Juenemann:

On January 30, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA certification #176503). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 2 and Repeat Level 2 findings were documented at your facility:

Repeat,Level 2 Non-Compliance:

1. One of seven random mammography reports did not contain an assessment category. Note: A listing of the official and approved alternate wording for mammography assessment levels is attached.

Level 2 Non-Compliance:

2. The time period between the previous and current physicist survey for your mammography machine (ACR designation = unit #1) exceeded 14 months. Note: The completion of a physicist survey is an

annual requirement. By policy this is not cited as a non-compliance until the interval exceeds 14 months.

The specific problems noted above appeared on your MQSA Facility Inspection report that was issued to your facility following the close of the inspection.

Because these conditions may by symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

FDA acknowledges a letter dated February 1, 2001, from Lillian Kochlin, R.T.(R)(M). This Warning Letter was prompted by the repeat nature of one of the non-compliances. The purpose of this Warning Letter is to formally alert senior management of the inspectional findings.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations. Due to the repeat nature of one of the non-compliances it is recommended that your corrective action contain a check-and-balance system to prevent an additional reoccurrence of this issue; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

James A. Rahto
Director
Minneapolis District

CHH TWG/ccl

Enclosure

xc: Lead Interpreting Physician
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